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| EXAMINER | | | | |
| DOUGHERTY, SEAN PATRICK | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,519

Applicant(s)

DUDA ET AL.

Examiner

SEAN P. DOUGHERTY

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This is the initial Office action after a request for continued examination based on the 10/553519 application filed 08/01/2006. Claims 26-50 are currently pending and have been fully considered below.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/18/2009 has been entered.

Response to Amendment

The amendment(s) filed 06/18/2009 by Applicant have been considered by Examiner. Examiner acknowledges amended claim(s) 26. The previous rejection(s) of claim(s) are maintained. The following reiterated ground(s) of rejection(s) are set forth below:

Priority

This application is a national stage entry of PCT/DE04/00839.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-50 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Where the individual musculoskeletal strains determined from musculoskeletal parameters of a patient including "stretching in bone, a muscle, a cartilage, a tendon, a ligament, a joint, or a connective tissue that results in injury, weakening, or overexertion of a joint or tissue of the musculoskeletal system" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

"Bone measurements and their densities, the points of gravity of the bones and other inertia parameters", "parameters" and "dimensions" of bone are established in paragraph 31 of the disclosure of the printed publication of the instant application, however, the disclosure is silent to any "stretching of bone". Therefore, the disclosure

does not enable determining individual musculoskeletal strains from the musculoskeletal parameters that involved the "stretching of bone" because such has not been disclosed in the disclosure of the instant application.

"Interventions on ligament structures" is established in paragraph 9 of the disclosure of the printed publication of the instant application, however, the disclosure is silent to any "stretching" of "ligaments". Therefore, the disclosure does not enable determining individual musculoskeletal strains from the musculoskeletal parameters that involved the "stretching" of "ligaments" because such has not been disclosed in the disclosure of the instant application.

"Individual musculoskeletal parameters of the patient are determined first, particularly by automatically measuring anthropometric parameters and/or the position and/or alignment of joints" is established in the abstract of the instant application, however, the disclosure is silent to any "stretching" of "joints". Therefore, the disclosure does not enable determining individual musculoskeletal strains from the musculoskeletal parameters that involved the "stretching" of "joints" because such has not been disclosed in the disclosure of the instant application.

The disclosure is silent to the musculoskeletal parameters that determined by way of the "muscle", "cartilage", "tendon" and "connective tissues". Additionally, the disclosure is silent to the "stretching" of any of the "muscle", "cartilage", "tendon" and "connective tissues". Therefore, the disclosure does not enable determining individual musculoskeletal strains from the musculoskeletal parameters that involved the

"stretching" of any of the "muscle", "cartilage", "tendon" and "connective tissues" because such has not been disclosed in the disclosure of the instant application.

The disclosure is silent to any type of any stretching of "a bone, a muscle, a cartilage, a tendon, a ligament, a joint, or a connective tissue" that results in "injury, weakening, or overexertion of a joint or tissue of the musculoskeletal system". Examiner is unable to determine any type of stretching that results in injury, weakening, or overexertion of a joint or tissue of the musculoskeletal system because such has not been disclosed in the disclosure of the instant application. The disclosure is also silent to a musculoskeletal "system".

Claims 26-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

"Where the individual musculoskeletal strains are a stretching in a bone, a muscle, a cartilage, a tendon, a ligament, a joint, or a connective tissue of the musculoskeletal system of the patient that results in injury, weakening, or overexertion of a joint or tissue of the musculoskeletal system" in claim 1 is considered new matter by Examiner as such subject matter was not described in the specification at the time the application was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 27, 31-38 and 40-50 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,205,411 to DiGioia, III et al. (hereinafter "DiGioia").

Regarding claim 26, DiGioia discloses a method for simulating musculoskeletal strains on a patient for monitoring surgical the method comprising the steps of:

(a) determining individual musculoskeletal parameters of the patient (interventions ("pre-operative planner 12" col. 5, ll. 63-67),

(b) automatically determining the individual musculoskeletal strains from the determined musculoskeletal parameters of the patient (col. 5, ll. 67 to col. 6, ll. 5), wherein the individual musculoskeletal strains are a stretching in a bone, a muscle, a cartilage, a tendon, a ligament, a joint, or a connective tissue of the musculoskeletal system of the patient that results in injury, weakening, or overexertion of a joint or tissue of the musculoskeletal system - note that movement and motion of a joint would induce stretching of bone, a muscle, a cartilage, a tendon, a ligament, a joint, or a connective tissue of the musculoskeletal system,

(c) for the automatic determination of the individual musculoskeletal strains, comparing the individual and varied musculoskeletal parameters with musculoskeletal reference parameters filed in a strain database constructed with empirical data (col. 7,

lines 48-50), and musculoskeletal reference strains corresponding to the musculoskeletal reference parameters are determined as the individual musculoskeletal strains (col. 7, lines 19-33), the musculoskeletal reference parameters being present as discrete values in the strain database (col. 5, line 67 to col. 6, lines 5; col. 6, lines 9-12; col. 7, lines 36-40; col. 7, lines 54-57) and the musculoskeletal reference parameters being compared with the individual musculoskeletal parameters by means of functional relationships (col. 7, lines 46-63) and (d) evaluating the individual musculoskeletal strains in respect of at least one target criterion (col. 7, lines 27-29).

Regarding claim 27, DiGioia discloses the method as claimed in claim 26, further comprising the steps of (e) varying at least one of the individual musculoskeletal parameter (col. 7, lines 34-36) to obtain a varied musculoskeletal parameter (col. 7, lines 46-50), (f) subsequently automatically determining the individual musculoskeletal strains taking into consideration the at least one varied musculoskeletal parameter (col. 7, lines 19-33) and (g) subsequently evaluating the individual musculoskeletal strains in respect of the at least one target criterion (col. 7, lines 48-50).

Regarding claim 31, DiGioia discloses the method as claimed in claim 27, wherein the variation of the individual musculoskeletal parameters in step e. is carried out taking into consideration predefinable data for implants (col. 7, lines 27-33).

Regarding claim 32, DiGioia discloses the method as claimed in claim 26, wherein the individual musculoskeletal strains are calculated from the determined individual musculoskeletal parameters (col. 7, lines 15-18).

Regarding claim 33, DiGioia discloses the method as claimed in claim 32, wherein a biomechanical and/or a mathematical model is used as a basis for the calculation of the individual musculoskeletal strains (col. 7, lines 19-22).

Regarding claim 34, DiGioia discloses the method as claimed in claim 33, wherein the biomechanical and/or mathematical model is adapted to the individual musculoskeletal parameters (col. 7, lines 22-26).

Regarding claim 35, DiGioia discloses the method as claimed in claim 33, wherein the biomechanical and/or mathematical model is chosen on the basis of the determined individual musculoskeletal parameters from at least one database (col. 7, lines 27-45).

Regarding claim 36, DiGioia discloses the method as claimed in claim 34, wherein the individual musculoskeletal strains are calculated with the aid of a musculoskeletal model taking into consideration the individual patient anatomy (col. 7, lines 11-18).

Regarding claim 37, DiGioia discloses the method as claimed in claim 26, wherein the individual musculoskeletal strains are visualized for evaluation (col. 6, lines 17-21).

Regarding claim 38, DiGioia discloses the method as claimed in claim 26, wherein the individual musculoskeletal strains are presented on the basis of an anatomical model, particularly in graph form and/or numerically (col. 6, lines 50-61; col. 7, lines 11-22).

Regarding claim 40, DiGioia discloses the method as claimed in claim 26, wherein the individual musculoskeletal parameters of the patient are determined by measurements (col. 6, lines 50-54).

Regarding claim 41, DiGioia discloses the method as claimed in claim 40, wherein at least one of the individual musculoskeletal parameters is measured automatically (col. 6, lines 55-58).

Regarding claim 42, DiGioia discloses the method as claimed in claim 26, wherein individual movement parameters, particularly gait parameters, are determined (col. 7, lines 19-33), and these are used for the automatic determination of individual musculoskeletal strains (col. 7, lines 46-63).

Regarding claim 43, DiGioia discloses the method as claimed in claim 42, wherein the individual gait parameters are determined from personal data stored in a database and/or are recorded individually for one person (col. 7, lines 48-63).

Regarding claim 44, DiGioia discloses the method as claimed in claim 26, wherein the position and/or orientation of joints are used for a navigation system for computer-assisted surgery and/or the data from a navigation system are used for computer-assisted surgery (col. 6, lines 24-48).

Regarding claim 45, DiGioia discloses a device for evaluating musculoskeletal strains on a patient, with means for carrying out the method as claimed in claim 26 (apparatus, 10).

Regarding claim 46, DiGioia discloses a movement analysis system coupled to the device as claimed in claim 45 (col. 6, lines 24-48).

Regarding claim 47, DiGioia discloses a navigation system for computer-assisted surgery for carrying out the method as claimed in claim 26 (col. 6, lines 24-48).

Regarding claim 48, DiGioia discloses a method as claimed in claim 26, wherein the musculoskeletal parameters are automatically measured anthropometric parameters (col. 7, lines 1-10).

Regarding claim 49, DiGioia discloses a method as claimed in claim 26, wherein the target criterion include contact forces, degree of joint movement, fragment movements of a fracture or any combination thereof (col. 7, lines 46-50).

Regarding claim 50, DiGioia discloses a method as claimed in claim 26, further comprising the step of automatically deriving anthropometric parameters from a system for computer-assisted surgery (col. 7, lines 46-63).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 28, 29 and 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,205,411 to DiGioia, III et al. (hereinafter "DiGioia").

Regarding claim 28, DiGioia discloses the method as claimed in claim 27, wherein a specific target value of at least one target criterion is reached. DiGioia does not appear to explicitly disclose wherein step (e) to (g) are repeated until a specified target value of at least one target criterion is reached. However, it would have been obvious to one of ordinary skill in the art to repeat the steps e. to g. until a specified target value of at least one target criterion is reached as this process is inherent as disclosed by DiGioia. DiGioia establishes the variation of size and orientations of implant components along with the variation of test positions (col. 7, lines 34-36) and simulating various conditions to calculate a range of motion for each condition (col. 7, lines 46-48), comparing each value to a predetermined range of motion to determine an optimized calculated range (col. 7, lines 48-53). It is inherent from the disclosure of DiGioia that steps e. to g. are repeated as this would be done to determine the calculated range from each of the simulations of various conditions to determined the optimized range.

Regarding claim 29, DiGioia discloses the method as claimed in claim 28, wherein the individual and varied musculoskeletal parameters corresponding to the target value are output on an output unit, stored in a storage unit and/or transferred to a computer-assisted surgery system and/or to a surgical navigation system (col. 6, lines 24-48).

Regarding claim 30, DiGioia discloses the method as claimed in claim 28, wherein the individual and varied musculoskeletal parameters corresponding to the target value serve as a basis for planning a surgical intervention, the positioning of components or the decision regarding the removal of temporary implants (col. 6, lines 24-48).

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,205,411 to DiGioia, III et al. (hereinafter "DiGioia") US 2005/0203504 to Wham et al (hereinafter "Wham").

Regarding claim 39, DiGioia discloses the method as claimed in claim 26, wherein by evaluation of the individual musculoskeletal strains, a rehabilitation process is evaluated and/or managed (col. 6, lines 21-23). DiGioia does not appear to disclose the method as claimed in claim 26, wherein by evaluation of the individual musculoskeletal strains, a rehabilitation process is evaluated and/or managed, particularly by means of Internet access. However, Wham, a reference in analogous art discloses the method as claimed in claim 26, wherein by evaluation of the individual musculoskeletal strains, a rehabilitation process is evaluated and/or managed, particularly by means of Internet access (§0061).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of DiGioia and Wham before him or her to modify the evaluation and/or managing of the rehabilitation process of DiGioia to be evaluated and/or managed by means of Internet access of Wham. The motivation for doing so

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would have been to include instrument operating information, mappings, diagnostic information, algorithms or programs which are updated on a regular basis and downloaded to the generator as needed during surgery (Wham: ¶0061) which can be performed remotely from the surgical theater (DiGioia: col. 6, lines 21-23).

Response to Arguments

Applicant argues that the claims as amended overcome the cited prior art of reference. Examiner disagrees and respectfully refers Applicant to the rejection of the claims in view of the previously applied cited prior art of record, above.

Applicant contends in the page 6 of the Remarks filed 06/18/2009 that the characterization of "strain" is provided in the corresponding publication of the instant application. Examiner disagrees and respectfully submits that the disclosure of the instant application provides no support for the assertion that the limitation "strain" is narrowly limited to the definition of "stretching". A strain is characterized as the follow by Merriam-Webster Dictionary ([http://www.merriam-webster.com/medical/strain\[2\]](http://www.merriam-webster.com/medical/strain[2])):

"an act of straining or the condition of being strained: as **a**: excessive physical or mental tension; *also* : a force, influence, or factor causing such tension **b**: bodily injury from excessive tension, effort, or use <heart *strain*>; *especially* : one resulting from a wrench or twist and involving undue stretching of muscles or ligaments <back *strain*>—"

A skilled artisan at the time the invention was made would have broadly interpreted the limitation "strain" to claim a tension, effort or use and would not narrowly limit such phrase to claim merely a "stretching".

Furthermore, Applicant has apparently characterized the "musculoskeletal" to be narrowly limited to "a bone, a muscle, a cartilage, a tendon, a ligament, a joint, or a connective tissue of the musculoskeletal system". Examiner notes that the disclosure of the instant application is silent to any mention of a "musculoskeletal system".

Additionally, a skilled artisan at the time the invention was made would have interpreted

the limitation "musculoskeletal" to broadly suggest simply the skeletal portion of the body and the muscle portion of the body.

Applicant argues that the DiGioia patent fails to disclose a database for storing experimental strain values for different musculoskeletal parameters such as size of the femur, the tibia, the range of motion, the different angles between body members, the size of artificial implants, etc. Examiner disagrees and respectfully submits that the limitations on which the Applicant relies (i.e., "experimental" strain values and "size of the femur, the tibia, the range of motion, the different angles between body members") are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not. Examiner notes that DiGioia does establish a strain database with empirical data (col. 7, lines 48-50), as predetermined ranges of motions are considered empirical data.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736